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AUDIT REPORT FOR DENMARK

SEPTEMBER 7 THROUGH 28, 2000

April 26, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Denmark's meat inspection system from September 7 through 28, 2000. Nine of the 97 establishments certified to export meat to the United States were audited. Six of these were slaughter and processing establishments; the other three were conducting only processing operations.

The last audit of the Danish meat inspection system was conducted in May 1999. Eleven establishments were audited: eight (Ests. 13, 14, 28, 32, 71, 91, 95, and 469) were acceptable, two (Ests. 15 and 53) were evaluated as acceptable/re-review, and one (Est. 20) was unacceptable. The deficiencies reported at that time included cross-contamination, less-than-zero tolerance for fecal contamination, maintenance and cleaning of product-contact surfaces (these had all been adequately addressed), inadequacies in post-mortem inspection procedures, and inadequate documentation of SSOPs (problems were again found regarding the latter two deficiencies).

Due to the occurrence of a confirmed case of Bovine Spongiform Encephalopathy (BSE) in Denmark early in 2000, beef products were ineligible for export to the U.S. at the time of this audit. Pork products were eligible without restriction.

During the period from January 1 to August 31, 2000, Danish establishments exported 96,375,819 pounds of pork products to the U.S.; causes of rejections at U.S. ports of entry included labeling defects (0.1% of the total), violative net weight (0.08%), transportation damage (0.05%), processing defects and contamination (0.03% each), missing shipping marks (0.02%), and pathology (0.003%).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Danish national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities and audits of records from sixteen randomly-selected establishments that were not visited on-site. The third was conducted by on-site visits to establishments. The fourth was a visit to four laboratories, one performing analytical testing of field samples for the national residue testing program, and the other three culturing field samples for the presence of microbiological contamination with *Salmonella.*

Denmark's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the FSIS auditor (hereinafter called "the Auditor") evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The Auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in all nine of the establishments audited on-site; two of these (Ests. 28 and 47) were recommended for re-review. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in this report.

As stated in the Background section, the problems identified during the previous FSIS audit had been adequately addressed, except that inadequacies were again found regarding post-mortem inspection procedures and inadequate documentation of SSOPs. Other problems identified during this new audit included lack of monthly internal reviews of establishments, incomplete ante-mortem inspection procedures; non-implementation of the requirement for pre-shipment document reviews; and inadequate light intensity at post-mortem inspection stations, monitoring and verification of condensation control, and maintenance and cleaning of over-product structures.

Entrance Meeting

On September 7, an entrance meeting was held in the Mørkhøj (Copenhagen) offices of the Danish Veterinary and Food Authority (DVFA), and was attended by Dr. Kristian Hermansen, Asst. Chief Veterinary Officer and head of the Unit for Export Equivalence and Certification; Dr. Birgitte Povlsen, Senior Veterinary Officer and Head of the Division for Import/Export; Dr. Jens Munk Ebbesen, Deputy Chief, Division for Import/Export; Dr. Henning Pedersen, Veterinary Officer, Division for Import/Export; Dr. Justin Ajufo, Veterinary Officer, Division for Food Safety; Dr. Mette Hjulmand-Lassen, Veterinary Officer, Division for Food Safety; Mr. Finn Haunstrup Clemmensen, Head of the Division for Control Coordination; Dr. Mette Espersen, Veterinary Officer, Institute for Food Safety

and Toxicology; Mr. Flemming Kærby, M.Sc, Institute for Food Research and Nutrition; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. Topics of discussion included the following:

1. The Auditor provided a copy of the current Enforcement Quarterly Report and informed the DVFA officials where it could be located on the FSIS home page. He inquired whether Denmark also makes similar information available to the public; the Danish officials replied in the affirmative: the most recent one had been published in 1998; another was in progress, and was expected to be published by the end of the fiscal year. They further stated that the majority of the effort was going toward making the information available on the Internet, at DVFA's Website: www.foedevaredirektoratet.dk/Kontrolinformation. Each inspection report for all slaughterhouses, processing plants, supermarkets, and all other food producers and sellers was planned to be made available to the general public via the Internet. Each month, a publication covering all fines, product bans, or production suspensions, is available to the public.

2. The Auditor provided copies of the data-collection instruments he would be using in the audits of the individual establishments (Attachments A, B, C, and D).

Headquarters Audit

DVFA had undergone a reorganization, effective January 1, 2000, and was under the control of a new Director General. One of the major changes was that, before the reorganization, supervisory veterinarians from the two District Offices performed the monthly internal reviews of the various establishments. Since 1/1/00, the internal reviews of the establishments became the responsibility of the eleven new Regional Authorities.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The Auditor observed and evaluated the process.

The Auditor conducted a review of inspection system documents pertaining to the establishments listed for records review. This records review was conducted at the headquarters or the inspection service or at a district or regional office. The records review focused primarily on food safety hazards and included the following:

- Documentation of Denmark's species verification policy and program
- Summaries of enforcement actions, including examples of criminal prosecution, consumer complaints, recalls, and seizure and control of noncompliant product
- The training program for DVFA inspectors
- Implementation documents such as regulations, notices, directives and guidelines
- Explanatory field notifications for pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing

No concerns arose as a result the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Denmark as eligible to export meat products to the United States were full-time DVFA employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Ninety-seven Danish establishments were certified to export meat products to the United States at the time this audit was conducted. Nine establishments were visited for on-site audits. In all of these, both DVFA inspection system controls and establishment system controls were adequate, or corrective actions were taken, to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected on the risk areas of methodology, government oversight of accredited and approved laboratories, and intra-laboratory quality assurance procedures, including sample handling.

The Regional Veterinary and Food Authority Laboratory in Ringsted was audited on September 8, 2000. This laboratory was performing the field testing for chemical residues and confirmation analysis of samples submitted from the field for which screening tests for antibiotics have had positive results. Effective controls were in place for sample handling and frequency, data reporting, tissue matrices for analysis, equipment operation and print-outs, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

At the time of this audit, Denmark had corresponded with FSIS in Washington, D.C. regarding the equivalence of a thirty-day turnaround time for analysis of field samples for chemical residues and was waiting for a determination. Documents provided indicated that, for the period of January 1 through September 1, 2000, 75% of these field samples were analyzed within 30 days, and 96% were completed within 60 days.

Denmark's microbiological testing for *Salmonella* was being performed in government laboratories. Three of these, the Regional Veterinary and Food Authority Laboratories in Aalborg, Ringsted, and Northeast Sjælland, were audited. No concerns arose as a result of the audits of these three laboratories.

Establishment Operations by Establishment Number

The following operations were being conducted in the nine establishments visited:

Beef and pork slaughter and cutting, cooked sausage production, and pork curing – Est. 47
Beef and pork slaughter, boning, and cutting, and pork curing – Est. 15
Pork and (not for the USA) chicken processing and canning – Est. 220
Pork slaughter, boning, and cutting, and edible rendering – Est. 53
Pork slaughter, cutting, and curing – Ests. 28 and 79
Pork slaughter, boning, and cutting – Est. 319
Pork boning and cutting – Est. 337
Pork cutting and curing – Est. 469

SANITATION CONTROLS

Based on the on-site audits of establishments, Denmark's inspection system had controls in place for water potability records; chlorination procedures; back-siphonage prevention; hand-washing facilities; sanitizers; separation of establishments; pest control and monitoring; temperature control; operational and inspectors' work space; ventilation; ante-mortem facilities; outside premises; personal dress and habits; prevention of cross-contamination; product transportation; pre-operational and operational sanitation activities; and waste disposal.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements, with the following exceptions:

Product Protection and Handling

1. Condensation contaminating or endangering exposed product was not adequately controlled in six Establishments (28, 47, 53, 319, 337, and 469: see the individual establishment reports for details). Corrective actions by establishment management were prompt in all but Est. 28, in which corrective actions were ensured by the DVFA officials.

2. Maintenance and cleaning of over-product structures had been neglected to varying degrees in Ests. 15, 28, 79, and 337. In all cases, assurances of prompt attention were given, and increased frequency of maintenance, cleaning, and monitoring was scheduled.

3. The observed reconditioning procedure for dropped meat was inadequate in Est. 28: the written procedure in the SSOP was not being followed. This was identified by the DVFA

official leading the audit, who ordered that dropped meat could no longer be reconditioned until the establishment could demonstrate a reliably hygienic procedure.

Personnel Hygiene and Practices

In establishment 28, two employees failed to wash their hands upon entering production areas after having been outside the building, and in Est. 47, the butcher at the bung drop station failed to wash his hands after contaminating them, before continuing to work with exposed product. Corrective actions were taken immediately by establishment officials.

Documentation

Daily records were being generated in Est. 319, but there was little or no documentation of any operational sanitation activities, corrective actions, or preventive measures in one of the areas where serious condensation was observed during the on-site audit. The establishment representative said that operational problems were not documented.

In the establishment records audited from Ests. 62 and 65, documentation of pre-operational sanitation observations and corrective actions was found to be inadequate. This had been previously identified and documented by the Veterinarian-In-Charge in Est. 65.

The DVFA officials gave assurances that improved documentation of sanitation activities in these three establishments would be implemented promptly by the establishments and verified by the inspection personnel.

ANIMAL DISEASE CONTROLS

With the exceptions listed below, Denmark's inspection system had controls in place to ensure adequate animal identification, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

1. FSIS requires that all animals be observed from both sides in motion as an integral part of ante-mortem inspection. This was not being performed in Denmark. In all the slaughter facilities visited, the standard procedure was for the veterinarian to stand to one side of the animals as they were driven past him/her on their way from the receiving dock to the pens. The Auditor explained the requirement, both during the establishment visits and in the exit meeting from the country. Dr. Justin Ajufo, Veterinary Officer, Division for Food Safety, explained, during this exit meeting, the *lege artis* Euopean Commision requirement, accord-ing to which there is no specific requirement for observation from both sides. However, the official conducting the ante-mortem inspection is required to conduct any further examina-tion he/she may deem necessary in the event that any abnormality is detected. He further stated that DVFA plans to propose FSIS recognition of this as equivalent in the near future. The auditor informed the DVFA officials that a mirror may be used for the purpose.

2. Light at the inspection surfaces at post-mortem inspection stations was found to be inadequate in four of the six slaughter establishments audited (15, 28, 47, and 79) and at the reinspection station in Est. 319.

3. Inadequate post-mortem inspection was found in Est. 47 (inadequate or missing incision and observation of lymph nodes).

The only incident of animal disease with public-health significance since the previous U.S. audit was the aforementioned case of BSE. A program had been developed and implemented to examine 15,000 cattle per year for BSE in the course of the next four years as follows:

1. All emergency-slaughtered animals over 24 months of age (approximately 2,500)
2. A random sample of all animals over 24 months of age that are killed or die (approx. 8,000)
3. A random sample of all slaughtered animals (approx. 1,400)
4. Animals exposed to the same feedlot as the BSE-diagnosed cow (approx. 3,100)
5. All suspicious cases (approx. 100-200)
6. All culled animals imported from the United Kingdom (approx. 20)

All animals are examined by the Western Blotting Method; additionally, samples from all suspicious cases are examined immuno-histochemically.

RESIDUE CONTROLS

Denmark's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Danish inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and use of chemicals.

Chemical compounds were stored under insanitary conditions in Establishments 15, 28, and 47. In all three cases, the accompanying DVFA officials rejected the rooms for storage of chemicals pending acceptable maintenance and cleaning.

SLAUGHTER/PROCESSING CONTROLS

The Danish inspection system had controls in place to ensure adequate humane handling and slaughter, ingredients identification, formulations, packaging materials, laboratory confirmation, label approvals, inspector monitoring, processing equipment and records, empty can inspection filling procedures, container closure exam, interim and post-processing handling, incubation procedures, and processing defect actions by establishment personnel, and processing control by inspection personnel.

The defect criteria sheets for boneless meat reinspection had not been updated to reflect the zero-tolerance policy for contamination with ingesta. The Auditor examined documents for several months previous to the audits in the establishments that were performing boneless

meat reinspection and found no instances in which any ingesta had been identified. DVFA officials gave assurances that the criteria sheets would be promptly updated.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems, in the establishments subjected to either on-site audit or document audit, was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements, with the following exceptions:

The requirement for pre-shipment document reviews, relating to critical limits having been met for the product included in the shipment, had not been understood in Denmark, and no formal pre-shipment document reviews were being performed in any of the Danish establishments, although some related documentation was being generated in Est. 65. The Auditor explained the exact nature of the requirement in detail both in the establishments and during the country exit meeting, and provided references to the applicable regulations and telephone numbers of experts who could be consulted regarding the development of the programs.

In Est. 319, two of three examples of documentation related to critical limits having been exceeded did not include written descriptions of corrective actions as required in the establishment's written HACCP program.

Testing for Generic *E. coli*

Six of the establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

Denmark had adopted the FSIS regulatory requirements for generic *E. coli* testing with the exception of the following different equivalent requirements:

1. SAMPLING TOOLS

   Denmark was using a gauze swab sampling tool. The gauze swab is a generally/internationally recognized sample collection tool for *E. coli* on meat or poultry product surfaces.

   The sampling tool is sensitive enough to gather *E. coli* that are present at the sample sites.

   The sampling tool does not contaminate the surfaces of the carcass.

2. ANALYTICAL METHODS: different methods.

Denmark was using an NMKL method to analyze for generic *E. coli*. This method is a quantitative method of analysis.

The method is approved by the AOAC International or an internationally recognized scientific organization.

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements.

Additionally, establishments had adequate controls in place to prevent meat products intended for Danish domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

The DVFA inspection system controls [animal identification, ante-and post-mortem inspection dispositions, control of restricted product and inspection samples, condemned and restricted product control, control and disposition of dead, dying, diseased or disabled animals, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), the importation of only eligible livestock or poultry from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other counties for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

Six of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Denmark had adopted the FSIS regulatory requirements for *Salmonella* testing with the exception of the following equivalent measures:

1. SAMPLE COLLECTOR: establishments take samples.

   The government of Denmark provides a clearly written sampling plan with instructions for sample collection and processing that is followed by all applicable export establishments.

   All applicable veterinarians are properly and uniformly trained; they train the establishment employees. The trained veterinarian observes the collection/storage/ transport procedures on a periodic, unannounced basis to ensure that FSIS requirements are met. The government ensures that establishment sample collection activities are appropriate. Sample verification is performed upon request by the DVFA where the official veterinarian collects samples and DVFA analyzes the sample.

   The government of Denmark uses the test results to monitor establishment performance over time.

   The government of Denmark takes immediate action any time an establishment fails to meet a *Salmonella* performance standard.

2. LABORATORIES: private laboratories analyze samples.

   The laboratories are independent non-government or establishment laboratories that are accredited by the government of Denmark. The laboratories are required to participate in performance testing to ensure laboratory analyses are properly performed. Establishment labs are under the direct supervision of the on-site veterinarian.

   All accredited laboratories have a formal program to ensure that lab personnel are properly trained, there are suitable facilities and equipment, there is a written quality assurance program, and there are adequate reporting and record keeping facilities.

   Test results are provided directly to the government veterinarian.

3. SALMONELLA TESTING STRATEGY.

   Denmark uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. The sampling methodology is based on a uniform system approach in all applicable export establishments. All U.S. export establishments are included in the sample pool. Denmark collects one sample per production day, grouped in sample sets of 55 samples (swine) and uses FSIS Performance Standards and enforcement procedures.

   Denmark uses a continuous, ongoing sampling program to determine when to initiate additional *Salmonella* testing. All products for which there is a U.S. performance standard are included in the sample pool.

Denmark's testing program has statistical criteria for evaluating test results.

The percentage of *Salmonella* positives over time meets the FSIS percentage of positives in the FSIS standard.

4. SAMPLING TOOLS.

The gauze pad sampling tool is used. This sampling tool is internationally recognized for sampling *Salmonella* on meat or poultry product surfaces.

The sampling tool is sensitive enough to gather *Salmonella* that are present at the sample sites.

The sampling tool does not contaminate the surfaces of the carcass.

Furthermore, the official veterinarian in each slaughter establishment takes an independent sample once weekly for *Salmonella* analysis. These official samples serve as verification of those taken by the establishments, and are analyzed at an official laboratory.

The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements.

Species Verification

At the time of this audit, Denmark was not exempt from the species verification requirement. The Auditor verified that species verification was being conducted in accordance with FSIS requirements.

Monthly Reviews

FSIS requires documented supervisory visits by a representative of the foreign inspection system to each establishment certified as eligible to export to the United States, not less frequently than one such visit per month, during any period when the establishment is engaged in producing products that could be used for exportation to the United States.

Before the DVFA reorganization went into effect on January 1, 2000, supervisory veterinarians from the two central Meat Inspection District Offices performed the monthly internal reviews of the various establishments. Subsequently, the internal reviews of the establishments are the responsibility of the eleven new Regional Veterinary and Food Control Authorities, and are usually performed by Chief Veterinarians in charge at neighboring slaughter establishments and sometimes in charge of a number of meat establishments.

The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the offices of the Regional Authorities.

During the transition period to the new system and the change in responsibility, internal reviews were conducted each month at only three establishments. The Auditor examined the

internal review reports for the establishments selected both for on-site audits and for document audits, and determined that the supervisory visits had been missed for one month in three establishments, for two months in seven establishments, for three months in one establishment, for four months in three establishments, and for five months in three establishments (one of the latter was a cold-storage facility, one was a packaging operation with no boning or cutting, and the other was a small establishment with 15 employees, conducting beef cutting and re-packing of hams). The requirement that the internal reviews are performed each month when U.S.-eligible production is conducted was emphasized during the meetings with inspection personnel both in the field and in the exit meeting in Copenhagen. The DVFA officials gave assurances that they were aware of the requirement and would ensure that they would be conducted on a monthly basis, at a minimum.

Enforcement Activities

At the Auditor's request, the Danish officials provided a printout of an extensive summary of DVFA's enforcement activities in the form of a compliance report from their Website covering the months of June and July 2000 for his review.

Exit Meeting

An exit meeting was conducted in Copenhagen on September 28. The Danish participants were Dr. Kristian Hermannsen, Asst. Chief Veterinary Officer and head of the Unit for Export Equivalence and Certification; Dr. Birgitte Povlsen, Senior Veterinary Officer and Head of the Division for Import/Export; Dr. Jens Munk Ebbesen, Deputy Chief, Division for Import/Export; Dr. Henning Pedersen, Veterinary Officer, Division for Import/Export; Dr. Justin Ajufo, Veterinary Officer, Division for Food Safety; Mr. Flemming Kærby, M.Sc, institute for Food Research and Nutrition; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. The following topics were discussed:

1. The FSIS requirement for documented monthly supervisory visits to all establishments producing U.S.-eligible product was discussed in detail. The DVFA officials assured the Auditor that they were aware of the requirement, and indicated that this would be accomplished on a regular basis.

2. Ante-mortem inspection is required from both sides of animals at rest and in motion. Dr. Ajufo explained the *lege artis* EU requirement, according to which there is no specific requirement for observation from both sides. However, the official conducting the ante-mortem inspection was required to conduct any further examination he/she may deem necessary in the event that any abnormality is detected. DVFA officials said they planned to seek FSIS recognition of this as equivalent in the near future.

3. None of the establishments had been aware of the requirement for Pre-shipment document reviews. A draft version of a document for this purpose was prepared by one of the Danish Crown representatives who had been present during several on-site audits, and was shown to the Auditor at the exit meeting.

4. The other deficiencies found in the course of the audits were discussed, and DVFA officials gave assurances that:

   · Defect criteria sheets for boneless meat reinspection would be promptly updated to reflect the zero-tolerance policy for contamination with ingesta,

   · Light intensity at the inspection surfaces at post-mortem inspection stations and at reinspection stations would be monitored regularly for compliance with the requirements,

   · Monitoring and verification of condensation control would be improved in the six Establishments (28, 47, 53, 319, 337, and 469) where problems were noted,

   · Maintenance and cleaning of over-product structures would be monitored with increased frequency in Ests. 15, 28, 79, and 337,

   · Chemical storage areas in all establishments certified to export to the U.S. would be inspected for possible insanitary conditions, and

   · More effort would be devoted by inspection personnel to ensure that the establishments were adequately documenting pre-operational and operational sanitation activities, findings, corrective actions, and preventive measures, and also that the documentation created accurately reflects the actual conditions found in the establishments.

CONCLUSION

The inspection system of Denmark was found to have effective controls, or adequate corrective actions were taken, to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Nine establishments were audited on-site: seven were acceptable and two were evaluated as acceptable/re-review. The deficiencies encountered during the on-site establishment audits were adequately addressed to the Auditor's satisfaction.

Dr. Gary D. Bolstad — (Signed) *Dr. Gary D. Bolstad*
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing
D. Data collection instrument for *Salmonella* testing

Attachment A-1

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

	1	2	3	4	5	6	7	8
15	√	√	√	√	√	√	√	√
28	√	√	√	√	√	√	√	√
47	√	√	√	√	√	√	√	√
53	√	√	√	√	√	√	√	√
79	√	√	√	√	√	√	√	√
220	√	√	√	√	√	√	√	√
319	√	√	√	√	√	√	Inadeq.*	√
337	√	√	√	√	√	√	√	√
469	√	√	√	√	√	√	√	√

*319: Daily records were being generated, but there was little or no documentation of any operational sanitation activities, corrective actions, or preventive measures in one of the areas where serious condensation was observed during the audit. The establishment representative said that operational problems were not being documented.

Attachment A-2

Documentation of SSOPs was also audited from the following establishments that were not visited on-site:

	1	2	3	4	5	6	7	8
25	√	√	√	√	√	√	√	√
29	√	√	√	√	√	√	√	√
32	√	√	√	√	√	√	√	√
41	√	√	√	√	√	√	√	√
58	√	√	√	√	√	√	*	√
62	√	√	√	√	√	√	Inadeq.*	√
65	√	√	√	√	√	√	Inadeq.*	√
85	√	√	√	√	√	√	*	√
177	√	√	√	N/A*	√	√	√	√
190	√	√	√	√	√	√	not seen*	√
197	√	√	√	√	√	√	√	√
205	√	√	√	√	√	√	√	√
311	√	√	√	√	√	√	not seen*	√
315	√	√	√	√	√	√	√	√
318	√	√	√	√	√	√	not seen*	√
377	√	√	√	√	√	√	√	√

*58: Establishment documentation of operational sanitation findings and corrective actions was not available for audit, but the Veterinarian-In-Charge gave assurances that they were generated as required.

*62, 65: Establishment documentation of pre-operational sanitation observations and corrective actions was inadequate. This had been identified and documented by the Veterinarian-In-Charge in Est. 65.

*85: Establishment documentation of pre-operational sanitation observations and corrective actions was done daily, but independent DVFA reports contained observations not indicated in establishment reports.

*177: This was a cold-store facility. There were no product-contact surfaces.

*190, 311, 318: Examples of the establishment's daily documentation were not available for audit, but the DVFA officials gave assurances that they were generated as required.

Attachment B-1

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing and documenting pre-shipment document reviews as required.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

Est. #	1. Flow diagram	2. Haz. analysis –all ID'ed	3. Use & users includ-ed	4. Plan for each hazard	5. CCPs for all hazards	6. Mon-itoring is spec-ified	7. Corr. actions are des-cribed	8. Plan valida-ted	9. Ade-quate verific. proced-ures	10. Ade-quate docu-menta-tion	11. Dat-ed and signed	12. Pre-ship-ment doc. re-views
15	√	√	√	√	√	√	√	√	√	√	√	no
28	√	√	√	√	√	√	√	√	√	√	√	no
47	√	√	√	√	√	√	√	√	√	√	√	no
53	√	√	√	√	√	√	√	√	√	√	√	no
79	√	√	√	√	√	√	√	√	√	√	√	no
177	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
220	√	√	√	√	√	√	√	√	√	√	√	no
319	√	√	√	√	√	√	Occas*	√	√	√	√	no
337	√	√	√	√	√	√	√	√	√	√	√	no
469	√	√	√	√	√	√	√	√	√	√	√	no

*319: Two of three examples of exceeding CCPs did not include corrective actions.

Attachment B-2

Documentation of HACCP plans was also audited from the following establishments that were not visited on-site:

Est. #	1. Flow diagram	2. Haz. analysis –all ID'ed	3. Use & users include-ed	4. Plan for each hazard	5. CCPs for all hazards	6. Mon-itoring is spec-ified	7. Corr. actions are des-cribed	8. Plan valida-ted	9. Ade-quate verific. Proced-ures	10. Ade-quate docu-menta-tion	11. Dat-ed and signed	12. Pre-ship-ment doc. re-views
25	√	√	√	√	√	√	√	√	√	√	√	no
29	√	√	√	√	√	√	√	√	√	√	√	no
32	√	√	√	√	√	√	√	√	√	√	√	no
41	√	√	√	√	√	√	√	√	√	√	√	no
58	√	√	√	√	√	√	√	√	√	*	√	no
62	√	√	√	√	√	√	√	√	√	√	√	no
65	√	√	√	√	√	√	√	√	√	√	√	partial*
85	√	√	√	√	√	√	√	√	√	√	√	no
177	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
190	√	√	√	√	√	√	√	√	√	*	√	no
197	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
205	√	√	√	√	√	√	√	√	√	√	√	no
311	√	√	√	√	√	√	√	√	√	√	√	no
315	√	√	√	√	√	√	√	√	√	√	√	no
318	√	√	√	√	√	√	√	√	√	*	√	no
377	√	√	√	√	√	√	√	√	√	√	√	no

*58: The responsible individual was documenting that the thermographs registered cooler temperatures within critical limits, but no observations were recorded by the establishment relating to the CCP of fecal contamination prevention.

*65: Some documentation approximating pre-shipment document reviews was being prepared, and a formal PSDR procedure was being developed.

*190, 318: No examples of daily documentation was provided; DVFA assured they were generated.

Attachment C-1

Data Collection Instrument for Generic *E. coli* Testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
15	√	√	√	√	√	√	√	√	√	√
28	√	√	√	√	√	√	√	√	√	√
47	√	√	√	√	√	√	√	√	√	√
53	√	√	√	√	√	√	√	√	√	√
79	√	√	√	√	√	√	√	√	√	√
177	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
220	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
319	√	√	√	√	√	√	√	√	√	√
337	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
469	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Documentation of *E. coli* testing programs was also audited from the following establishments that were not visited on-site:

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
25	√	√	√	√	√	√	√	√	√	√
29	√	√	√	√	√	√	√	√	√	√
32	√	√	√	√	√	√	*	√	√	√
41	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
58	√	√	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	√	√	√
65	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
85	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
177	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
190	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
197	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
205	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
311	√	√	√	√	√	√	√	√	√	√
315	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
318	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
377	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

*32: The rails were chosen at random; carcasses at the ends of the rails were sampled.

Attachment D-1

Data Collection Instrument for *Salmonella* testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of the documentation audited from the following establishments that were visited on-site were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
15	√	√	N/A	√	√	N/A
28	√	√	√	√	√	√
47	√	√	N/A	√	√	N/A
53	√	√	N/A	√	√	N/A
79	√	√	N/A	√	√	N/A
177	N/A	N/A	N/A	N/A	N/A	N/A
220	N/A	N/A	N/A	N/A	N/A	N/A
319	√	√	N/A	√	√	N/A
337	N/A	N/A	N/A	N/A	N/A	N/A
469	N/A	N/A	N/A	N/A	N/A	N/A

Attachment D-2

Documentation of *Salmonella* testing programs was also audited from the following establishments that were not visited on-site:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
25	√	√	N/A	√	√	N/A
29	√	√	N/A	√	√	N/A
32	√	√	N/A	√	√	N/A
41	N/A	N/A	N/A	N/A	N/A	N/A
58	√	√	N/A	√	√	N/A
62	√	√	N/A	√	√	N/A
65	N/A	N/A	N/A	N/A	N/A	N/A
85	N/A	N/A	N/A	N/A	N/A	N/A
177	N/A	N/A	N/A	N/A	N/A	N/A
190	N/A	N/A	N/A	N/A	N/A	N/A
197	N/A	N/A	N/A	N/A	N/A	N/A
205	√	N/A	√	√	√	N/A
311	√	√	√	√	√	√
315	N/A	N/A	N/A	N/A	N/A	N/A
318	N/A	N/A	N/A	N/A	N/A	N/A
377	N/A	N/A	N/A	N/A	N/A	N/A